



PTO/SB/21 (02-04)

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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/081,345
	Filing Date	February 22, 2002
	First Named Inventor	Karpf
	Art Unit	1623
	Examiner Name	Devesh Khare
Total Number of Pages in This Submission	Attorney Docket Number	20407 US1

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form	<input type="checkbox"/> Drawing(s)	<input type="checkbox"/> After Allowance communication to Group
<input type="checkbox"/> Fee Attached	<input type="checkbox"/> Licensing-related Papers	<input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences
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SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT		
Firm or Individual name	Samuel H. Megerditchian	
Signature		
Date	11/02/2004	

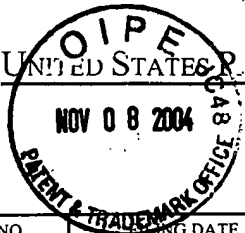
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Typed or printed name	Samuel H. Megerditchian	
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This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081,345	02/22/2002	Martin Karpf	20407 US1	2961

151 7590 07/14/2004

HOFFMANN-LA ROCHE INC.
PATENT LAW DEPARTMENT
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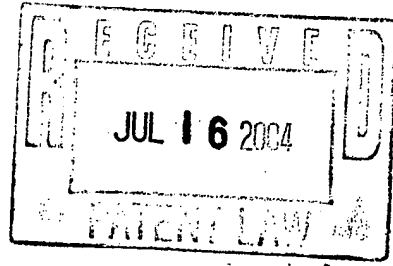
EXAMINER

KHARE, DEVESH

ART UNIT PAPER NUMBER

1623

DATE MAILED: 07/14/2004



Please find below and/or attached an Office communication concerning this application or proceeding.

RESPONSE DUE:	<u>November 14, 2004</u>
STATUTORY PERIOD EXPIRES:	<u>January 14, 2005</u>

Copy Sent to
Department PLP

Office Action Summary



Application No.

10/081,345

Applicant(s)

KARPF ET AL.

Examiner

Devesh Khare

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 2 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 2 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 6/18/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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The remarks and request for RCE filed on 05/24/2004, are acknowledged. Claims 3-13 have been cancelled. Claims 1 and 2 are currently pending in this application. In view of the applicant's remarks, the examiner withdraws the 35 U.S.C. 103(a) rejections as obvious over Kent et al. (U.S. 6,204,398), because Kent et al. does not suggest the use of magnesium halide catalyst in the transformation of an epoxide to a 2-aminoalcohol as is claimed in the pending process claims 1 and 2.

During the course of reconsideration of the application, a prior art reference not previously disclosed by the applicants or the examiner came to light (see rejection below).

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Auge et al. (Auge) (Tetrahedron Letters, 37(43), pp 7715-7716, 1996) in view of Karpf et al. (Karpf) (U.S. Patent 6,437,171).

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in

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the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). For applications filed on or after November 29, 1999, this rejection might also be overcome by showing that the subject matter of the reference and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person. See MPEP § 706.02(I)(1) and § 706.02(I)(2).

Claims 1 and 2 are drawn to a process for preparing a 2-aminoalcohol (III) by treating a 1,2-epoxide of formula (II) (claim 1) with an amine in the presence of a magnesium halide catalyst. Additional claim limitations include the amine of formula R^5NHR^6 wherein the amine is allylamine, diallylamine, benzylamine, dibenzylamine or trimethylsilyl amine and the magnesium halide catalyst is magnesium bromide diethyl etherate.

Auge teaches the aminolysis of oxiranes (1,2-epoxide) to produce β -amino alcohols (or 2-aminoalcohol) (abstract on page 7715). Auge discloses the reaction between various oxiranes and amines having the general structure of the formula R_3R_4NH

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wherein the epoxide of the oxirane is attacked by the said amine in presence of lithium triflate to produce the β -amino alcohols (page 7716, Table: Aminolysis of Oxiranes).

Auge does not suggest the use of magnesium halide catalyst in the reaction.

Karpf teaches a process for preparing 1, 2-diamino compounds by reacting 1,2-epoxides with an amine (col.2, lines 5-25). Karpf discloses that the reaction time of the said reaction can be reduced significantly with the use of magnesium halide catalyst (col. 6, lines 1-30). Karpf also discloses the amine of formula $R^5 NHR^6$ of the instant claim 2 (col. 5, lines 17-65). Furthermore, the 1,2-epoxide of formula II with various substituents is disclosed (col. 13, line 20). The 1,2-epoxide of formula II and the amine of formula $R^5 NHR^6$ are closely analogous to the applicant's claimed reactants of claims 1 and 2.

Therefore, one of ordinary skill in the art would have found the applicants process for preparing a 2-aminoalcohol, to have been obvious at the time the invention was made having the above references before him because Auge teaches the aminolysis of oxiranes (1,2-epoxide) to produce β -amino alcohols (or 2-aminoalcohol) and Karpf discloses that the reaction time of the said reaction can be reduced significantly with the use of magnesium halide catalyst, a skilled artisan would be motivated to make routine modifications to produce 2-aminoalcohol, an important class of compounds known for their pharmaceutical and biological properties (see Auge, page 7715, 1st para.).

Any inquiry concerning this communication or earlier communications from the

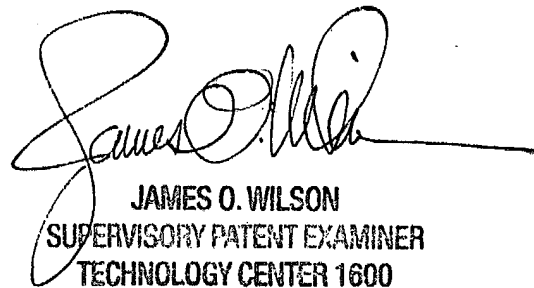
Art Unit: 1623

Examiner should be directed to Devesh Khare whose telephone number is (571)272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30.

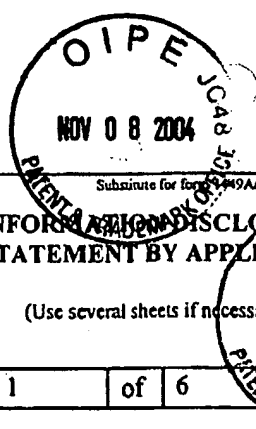
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D., J.D.
Art Unit 1623
July 2, 2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

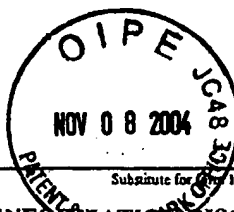


Substantive for form 19A/PTO INFORMATIONAL DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Complete if Known	
		Application Number	10/081,345
		Filing Date	February 22, 2002
		First Name Inventor	Martin Karpf
		Group Art Unit	1623
		Examiner Name	Devesh Khare
		Attorney Docket Number	20407 US1
Sheet	1	of	6

NON PATENT LITERATURE DOCUMENTS

Examiner Initials [*]	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
<i>mk</i>	C14	K.G. AKAMANCHI, et. al., "Diisopropoxyaluminium Trifluoroacetate: A New off the Shelf Metal Alkoxide Type Reducing Agent for Reduction of Aldehydes and Ketones," Synlett, 371-372 (1997)	
	C15	C. ANAYA de PARRODI, et. al. "Application of Phosphorylated Reagents Derived from N,N'-di-[(S)-α-phenylethyl]cyclohexane-1,2-diamines in the Determination of the Enantiomeric Purity of Chiral Alcohols," Tetrahedron: Asymmetry, 9, 2093-2099 (1998)	
	C16	C. ANAYA de PARRODI, et. al., "Synthesis of Enantiomerically Pure N-(S)-α-Methylbenzyl-β-Aminoalcohols by Regio-and Stereoselective Ring Opening of Epoxides," An Quim. Int. Ed., 92, 400-404 (1996)	
	C17	A.P.A. ARBORE, et. al., "A Rapid Approach to Amino-Acid Derivatives by [2,3]-Stevens Rearrangement" Synlett, 2, 236-38 (2000)	
	C18	J. AUGÉ, et. al., "Lithium Trifluoromethanesulfonate-catalysed Aminolysis of Oxiranes," Tetrahedron Lett. 37, 7715-7716 (1996)	
	C19	P. BARBARO, et. al., "New Enantiomerically Pure Aminoalcohols from (R)-α-Methylbenzylamine and Cyclohexene Oxide," Tetrahedron: Asymmetry 7, 843-850 (1996)	
	C20	M. BEATON, et. al., "Synthesis of 6-Amino-3,5-deoxyinositol 1-Phosphates via (1R,2R,4R,6S)-1,6 Epoxy-2,4-bis-benzyloxycyclohexane Aminolysis in Aqueous Ytterbium Triflate Solution," Tetrahedron Lett., 39, 8549-8552 (1998)	
<i>mk</i>	C21	F. BRION "On the Lewis Acid Catalyzed Diels-Alder reaction of Furan. Regio-and Stereospecific Synthesis of Substituted Cyclohexenols and Cyclohexadienols," Tetrahedron Letters, 23, 5299-5302 (1982)	
Examiner Signature	<i>Devesh Khare</i>		Date Considered 7/2/04

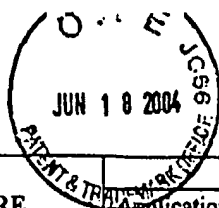
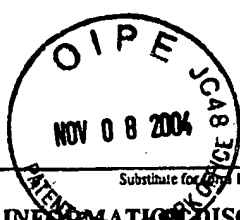
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¹Unique citation designation number. ²See attached Kinds of U.S. Patent Documents. ³Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶Applicant is to place a check mark here if English language Translation or abstract is attached.



INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Substrate for 35 USC 1449A/PTO	
		Complete if Known	
Application Number		10/081,345	
Filing Date		February 22, 2002	
First Name Inventor		Martin Karpf	
Group Art Unit		1623	
Examiner Name		Devesh Khare	
Attorney Docket Number		20407 US1	
Sheet	2	of	6

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mu	C22	F.M. CALLAHAN, et. al., "The Tertiary Buyl Group as a Blocking Agent for Hydroxyl Sulfhydryl and Amido Functions in Peptide Synthesis" J. Am. Chem. Soc. 85, 201-7 (1963)	
	C23	M. CANAS, et. al., "Regioselective Ring Opening of Chiral Epoxyalcohols by Primary Amines," Tetrahedron Lett. 32, 6931-6934 (1991)	
	C24	M. CHINI, et. al. "Metal Salts as New Catalysts for Mild and Efficient Aminolysis of Oxiranes," Tetrahedron Lett. 31, 4661-4664 (1990)	
	C25	M. CHINI, et. al. "Regioalternating Selectivity in the Metal Salt Catalyzed Aminolysis of Styrene Oxide," J. Org. Chem. 56, 5939-5942 (1991)	
	C26	J.M. CHONG, et. al., "Nucleophilic Openings of 2,3-Epoxy Acids and Amides Mediated by Ti(O-i-Pr) ₄ Reliable C-3 Selectivity," J. Org. Chem.. 50, 1560-1563 (1985)	
	C27	C.R. CLARK, et. al., "Highly Selective Opioid Analgesics. Synthesis and Structure-Activity Relationships of Novel N-[2-Aminocyclohexyl]aryl]acetamide and N-[2-Aminocyclohexyl]aryoxy]acetamide Derivatives," J. Med. Chem., 31, 831-836 (1988)	
	C28	G.E. COATES, et. al. "Some t-Butylmagnesium and Related Complexes. Reactions between Hydrides and Organomagnesium Compounds," J. Chem. Soc (A) 514-518 (1968)	
	C29	N. DE KIMPE, et. al., "Synthesis of 2,2-Dialkyl-1-aminocyclopropanecarboxylic Acids from α-Chloro Ketimines," J. Org. Chem. 55, 5777-5784 (1990)	
	C30	J.A. DEYRUP, et. al. "1,2,3-Oxathiazolidines-a New Heterocyclic System", J. Org. Chem 34, 175-179 (1969)	
	C31	M.J. EARLE, et. al. "A New Synthesis of Primary Amines Using tert-Butylamine as an Ammonia Equivalent: The Triflic Acid Catalysed Removal of N-tert-Butyl Groups from Carbamates," Synlett, 621-623 (1990)	
du	C32	D.F. EVANS, et. al., "Studies in Grignard Reagents. Part II. NNN'N'-Tetraethylethylene-diamine Grignard Adducts," J. Chem. Soc (A) 1648-1649 (1967)	



Substitute for Form 1449/APTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use several sheets if necessary)		Application Number	10/081,345
		Filing Date	February 22, 2002
		First Name Inventor	Martin Karpf
		Group Art Unit	1623
		Examiner Name	Devesh Khare
Sheet 3 of 6	Attorney Docket Number	20407 US1	

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mm	C33	M. FUJIWARA, et. al. "Tetraphenylstibonium Triflate as a Regio-and Chemoselective Catalyst in the Reaction of Oxiranes with Amines," Tetrahedron Lett., 30, 739-742 (1989)	
	C34	F. GARRO-HELION, et. al., "Mild and Selective Palladium(0)-Catalyzed Deallylation of Allylic Amines. Allylamine and Diallylamine as Very Convenient Ammonia Equivalents for the Synthesis of Primary Amines," J. Org. Chem. 58, 6109-6113 (1993)	
	C35	P.R. HALFPENNY, et. al. "Highly Selective κ -Opioid Analgesics. 2. Synthesis and Structure-Activity Relationships of Novel N-[2-Aminocyclohexyl]aryl]acetamide Derivatives," J. Med. Chem. 32, 1620-1626 (1989)	
	C36	J.Y. HAM, et. al., "A New Convenient Method for the Monoprotection of ω -alkanediamines," Bull. Korean Chem. Soc., 15, 1025-1027 (1994)	
	C37	G. HOFLE, et. al. "4-Dialkylaminopyridines as Highly Active Acylation Catalysts", Agnew Chem. Int. Ed. Engl., 17, 569-583 (1978)	
	C38	M. KARPf, et. al., "New, Azide-Free Transformation of Epoxides into 1,2-Diamino Compounds: Synthesis of the Anti-influenza Neuraminidase Inhibitor Oseltamivir Phosphate (Tamiflu)," J. Org. Chem. 66, 2044-2051 (2001)	
	C39	G.S. KAUFFMAN, et. al., "An Efficient Chiral Moderator Prepared from Inexpensive (+)-3-Carene: Synthesis of the HIV-1 Non-Nucleoside Reverse Transcriptase Inhibitor DPC 963," Org. Lett., 2, 3119-3121 (2000)	
	C40	R.N. LACEY, "The Acid-catalysed Heterolysis of Amides with Alkyl-Nitrogen fission (A _{AL})," J. Chem. Soc. 1633-1639 (1960)	

Subsisting in Form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

JUN 18 2004

NOV 08 2004

Complete if Known

Application Number	10/081,345
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Sheet 4 of 6

NON PATENT LITERATURE DOCUMENTS

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dm	C41	S. LEPPANEN, et. al., "Nucleophilic Reactivity; Part VIII. Kinetics of Reactions of Acetic Anhydride with Nucleophiles in Water," Acta Chem. Scand., 27, 3572-3578 (1973)	
	C42	G.E. MCCASLAND, et. al., "Stereochemistry of Aminocyclanols. Synthesis of <i>cis</i> Epimers via Oxazolines. The 2-Aminocyclopentanols," J. Am. Chem. Soc. 72, 2190-2195 (1950)	
	C43	S.P. MCMANUS, et. al., "The Synthesis of Aminoalcohols From Epoxides and Ammonia," Synthetic Communications 3, 177-180 (1973)	
	C44	M. MEGURO, et. al. "Ytterbium Triflate and High Pressure-mediated Ring Opening of Epoxides with Amines," J. Chem. Soc., Perkin Trans. 1, 2597-2601 (1994)	
	C45	M. MEGURO, et. al. "Ytterbium Triflate Catalyzed Ring Opening of Aziridines with Amines," Tetrahedron Lett., 35, 7395-7398 (1994)	
	C46	M. MOUSSERON, et. al., "No. 173.-Recherches en serie alicyclique(34 memoire)," Bull. Soc.Chim.Fr. 757-766(1952)	
	C47	K. NAKAJIMA, et. al., Studies on Aziridine-2-carboxylic Acid.I. Synthesis of the Optically Active-L-Aziridine-2-carboxylic Acid and its Derivatives," Bull. Chem. Soc. Jpn. 51, 1577-1578 (1978)	
	C48	M. POCH, et. al. "A Versatile Enantiospecific Approach to 3-Azetidinols and Aziridines," Tetrahedron Lett., 32, 6935-6938 (1991)	
	C49	G.H. POSNER, "Organic Reactions at Alumina Surfaces," Angew.Chem.Int.Ed.Engl.17, 487-496 (1978)	
	C50	G.H. POSNER, et. al. "Organic Reactions at Alumina Surfaces. Mild and Selective Opening of Epoxides by Alcohols, Thiols, Benzeneselenol, Amines, and Acetic Acid," J. Am. Chem. Soc. 99, 8208-8214 (1977)	
dm	C51	G.H. POSNER, et. al. "Organic Reactions at Alumina Surfaces, Mild and Selective Opening of Arene and Related Oxides by Weak Oxygen and Nitrogen Nucleophiles," J. Am. Chem. Soc. 99, 8214-8218 (1977)	

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Substitute for form 1449A/PTO		Complete if Known	
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		Group Art Unit	1623
		Examiner Name	Devesh Khare
		Attorney Docket Number	20407 US1
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NON PATENT LITERATURE DOCUMENTS

Examiner Initials ¹	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	
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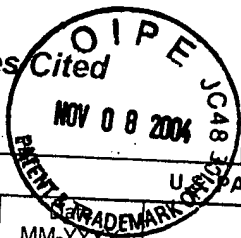
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	B	US-			
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*	U	Auge et al. Tetrahedron Letters, 37(43), pp 7715-7716, 1996.
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